

1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Hideaki HOSOKAWA et al.**

Serial No.: **09/594,577**

Group Art Unit: **1642**

Filed: **June 15, 2000**

Examiner: **G. Nickol**

For: **METHOD FOR DETECTION OF CARCINOEMBRYONIC ANTIGENS HAVING
A MODIFIED SUGAR CHAIN STRUCTURE**

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JAN 08 2003

PETITION UNDER 37 CFR 1.181

TECH CENTER 1600/2900

Commissioner for Patents
Washington, D.C. 20231

January 6, 2003

#12

Sir:

Applicants respectfully petition to the Commissioner in regard to the Office communication dated November 4, 2002. A petition for a one-month extension of time from December 4, 2002, to January 4, 2002, was filed on December 20, 2002.

STATEMENT OF FACTS

- 1) The application was filed on June 15, 2000, with 30 claims.
- 2) A Restriction Requirement was made in the Office action dated July 31, 2001, requiring restriction to Group 1, claims 1-13, 16-22; Group 2, claims 14-22; or group 3, claims 23-30. A species election was also required between antibody or lectin. It was further required that if antibody were selected that election be made between six listed antibodies (in reference to claims 7-8, 19-20 and 27-28). It was also required that if lectin were selected, that a lectin be elected from among 10 listed lectins (in reference to claims 9-10, 21-22, and 29-30).

3) A Response to the Restriction Requirement was filed on August 23, 2001, electing Group I (claims 1-13 and 16-22). The elected species were antibody, specifically anti-Le^a antibody. The election was made without traverse. Applicants indicated that claims 1, 2, 3, 4, 6, 7, 12, 13, 16 and 19 read on the elected species.

4) An Office action was issued on May 21, 2002, in which claims 1-4, 6, 7, 11-13, 16, 18 and 19 were rejected.

5) In response, Applicants submitted an Amendment dated August 12, 2002. In the Amendment, claims 1-30 were canceled and new claims 31-44 were added. (Actually, due to a typographical error, no claim 36 was submitted). Applicants explained in the Amendment that the new claims read on elected Restriction Group I and the elected species of antibody and anti-Le^a antibody.

6) An Office communication was issued on November 4, 2002, indicating that the Amendment of August 12, 2002, was non-responsive because it canceled all claims to the elected invention and that the added claims were not readable on the elected invention.

7) Applicants' representative, Daniel Geselowitz, conducted a telephonic interview with Examiner Nickol on December 13, 2002, requesting withdrawal of this finding and examination of claims 31-44. Examiner Nickol suggested a telephonic interview with his supervisor, Examiner Tony Caputa.

8) Applicants' representative, Daniel Geselowitz, conducted a telephonic interview with Examiners Caputa and Nickol on December 17, 2002, again requesting withdrawal of this finding and examination of claims 31-44. Examiner Caputa suggested placing arguments in a response to the Office action.

9) A timely Response (including a petition for a one-month extension) was filed on December 20, 2002.

Response
Hideaki HOSOKAWA et al.

U.S. Patent Application S.N. 09/594,577
Attorney Docket No. 000683

10) In a telephone conversation with Examiner Nickol on January 6, 2003, the Examiner indicated that he would not withdraw the finding of non-responsiveness, and he suggested that Applicants file a Petition in order to resolve this issue.

POINTS TO BE REVIEWED

The main point to be reviewed is whether new claims 31-44 in the Amendment of August 12, 2002, read on the restriction group and species elected by the Applicants in the Response dated August 23, 2001. Applicants assert that the restriction groups were defined in the Office action dated July 31, 2001, and that claims 31-44 fall within the elected restriction group and species.

Applicants here respectfully request reconsideration and withdrawal of the finding of non-responsiveness, and request entry of the Amendment of November 4, 2002. Applicants here reiterate their arguments to this effect, which were presented in the Response dated December 20, 2002.

Specifically, Applicants respectfully assert that: 1) claims 31-44 **do** properly read on the elected group and species as defined in the Office action of July 31, 2001; and 2) the reasoning behind the finding that claims 31-44 do not read on the elected group and species, given in the Office action of November 4, 2002, is improper.

The Office action dated November 4, 2002, indicated that the Amendment filed on August 8, 2002, canceling claims 1-30 and adding new claims 31-44, is considered non-responsive, because "the remaining claims are non-readable on the elected invention because they present additional method steps and new limitations which were not previously considered."

A telephone interview to discuss this issue was conducted between Daniel Geselowitz and Examiner Nickol on December 13, 2002, and a subsequent telephone interview with Examiner Nickol and Examiner Caputa was conducted on December 17, 2002. In the second interview, as a result of the discussion, Examiner Caputa requested that Applicants submit their remarks in a Response, and a Response was filed on December 20, 2002. Applicants here reiterate arguments from that Response.

1) New claims 31-44 fall within the definition of Restriction Group 1.

Applicants have elected Restriction Group I, defined in the restriction requirement in the Office action of July 31, 2001. That Office action (page 2) defines Group 1 as follows:

“1. Claims 1-13, 16-22 drawn to a method for detecting carcinoembryonic antigens (CEAs) or a method for detecting cancer comprising using an antibody against a constant region of CEA and [a] protein capable of recognizing a modified sugar chain structure of CEAs, classified in class 435, subclass 4, 7.1”

This restriction group definition is clearly based on the recitation of original claim 1, which recites a method “using an antibody against a constant region of carcinoembryonic antigens” and “a protein capable of recognizing a modified sugar chain structure of carcinoembryonic antigens.”

Applicants assert that new claims 31-44 all fall within the scope of the restriction group definition.

Specifically:

a) The preamble to independent claim 31 is “A method for detecting cancer ...,” consistent with the definition of Group 1. Moreover, the steps of claim 31 clearly involve a method for detecting carcinoembryonic antigens having a particular sugar chain structure.

b) Claim 31 recites adding "an antibody against a constant region of carcinoembryonic antigens." This is clearly "using an antibody against a constant region of carcinoembryonic antigens," as stated in the restriction group definition.

c) Claim 31 involves addition of "a first protein, said first protein being one that selectively binds to a first sugar chain structure" in step i)a), and "a second protein, said second protein being one that selectively binds to a second sugar chain structure different from said first sugar chain structure." At least one of these must be "[a] protein capable of recognizing a modified sugar chain structure of CEAs." Applicants note that, in response to a rejection under 35 U.S.C. 112, second paragraph in the Office action of May 21, 2002, the claim language has been amended to delete the word "modified," which was considered indefinite. This point is discussed further below.

Accordingly, **claims 31-44 can be seen to meet the definition of restriction group 1 and to fall within the scope of original claim 1.**

Applicants also note that in the Response dated August 23, 2001, Applicants elected the species of antibody, specifically anti-Le^a antibody, as required. All of claims 31-44 are consistent with this election. The "first protein" of claims 31-33 and 35 is clearly generic to antibody or anti-Le^a antibody. Claims 34 and 37 specifically recite that "the first protein" is an anti-Le^a antibody. Claims 38-44 all depend from claim 37 and also require that the "first protein" is an anti-Le^a antibody. Therefore, **all of the added claims are consistent with the elected species as well as the elected restriction group.**

2) The Rationale for the finding of Claims reading on Non-elected invention appears improper.

In the Office action of November 4, 2002, the Examiner states that the new claims are not readable on the elected invention because "they present additional method steps and new limitations which were not previously considered."

Applicants respectfully submit that the addition of method steps and new limitations to a claim in general only narrows the claim **within the original scope**. It is clearly permitted to add new dependent claims adding additional limitations in an Amendment, and such claims in general would not properly be found to no longer read on the invention of the base claim.

The Examiner (page 2, line 13) states: "Not only are the claims not readable on the elected invention for the reasons set forth above but the new claims also would be subject to further restriction requirements" It is certainly the prerogative of the Examiner to issue additional restriction requirements. Applicants respectfully submit, however, that the Examiner's indication that additional searching might be needed for the new claims, however, is **not** a finding that the new claims do not read on the elected invention. As noted above, the addition of a limitation, for example in a dependent claim, does not mean that the dependent claim does not read on the invention of the base claim, even if additional searching is required.

Applicants believe that the Office communication dated November 4, 2002, fails to give any indication that the newly submitted claims are inconsistent with the definition of Restriction group I (from the Office action of July 31, 2001) or that the new claims do not fall within the scope of original claim 1.

3) Regarding the Telephone interview with Examiners Nickol and Caputa on December 17, 2002.

In the telephone interview, Examiner Caputa raised the following points:

a) Original claim 31 is directed to the detection of an antigen, while claim 31 is directed to detection of cancer.

b) Original claim 1 uses a protein capable of recognizing a modified sugar chain structure of carcinoembryonic antigens, while claim 31 is directed to a protein that selectively binds to a sugar chain structure.

c) The term "modified sugar chain structure" is used in claim 1, while "first sugar chain structure" is used in claim 31.

In response, Applicants explained:

a) Restriction group 1, as defined (Office action of July 31, 2001), includes a method for detecting cancer, as recited in claim 31. Moreover, claim 31 clearly involves detection of carcinoembryonic antigens.

b) The "first protein being one that selectively binds to a first sugar chain structure" is clearly being used to bind to the sugar chain of carcinoembryonic antigens, as may be seen in claim 31, step i)b), regarding "detecting if a complex is formed of said first protein, said antibody and carcinoembryonic antigen." This clearly falls within the scope of original claim 1.

c) The term "modified" was the source of a rejection under 35 U.S.C. 112, second paragraph, in the Office action of May 21, 2002. Therefore, **by requirement of the Examiner**, it was necessary that the term "modified" be replaced with more definite wording. The original term "modified" was intended to mean "different", as may be seen from the present specification. The concept of the

Response
Hideaki HOSOKAWA et al.

U.S. Patent Application S.N. 09/594,577
Attorney Docket No. 000683

protein in claim 31 is the same as in original claim 1, but for clarity, claim 31 recites "a first sugar chain structure" and "a second sugar chain structure different from said first sugar chain structure", thereby eliminating any indefiniteness resulting from the term "modified sugar chain structure".

Summary: In the telephonic interview with Examiner Nickol on December 13, 2002, Examiner Nickol indicated that the determination of whether the recited invention of claims 31-44 fell within the elected restriction groups was "open for interpretation" and "kind of subjective." Applicants respectfully disagree, arguing that the finding of whether claims 31-44 do fall within the elected restriction group must be made based on the written definition of the restriction group given in the restriction requirement (Office action of July 31, 2001). Applicants submit that care was taken in the drafting of the new claims to ensure that these claims would fall within the elected restriction group and read on the elected species. Applicants have reviewed the claims in that regard here. Applicants submit that these new claims are entitled to be evaluated in this regard based on the written restriction requirement as stated in the Office action, and request a finding that claims 31-44 do fall within the elected defined restriction group.

Response
Hideaki HOSOKAWA et al.

U.S. Patent Application S.N. 09/594,577
Attorney Docket No. 000683

ACTION REQUESTED

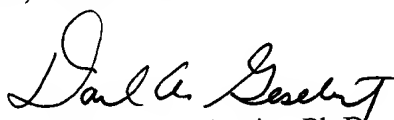
Applicants therefore respectfully request:

- 1) that the finding that claims 31-44 are directed to a non-elected invention be withdrawn;
- 2) that the Amendment of August 12, 2002, be entered; and
- 2) that a new Office action be issued after examining claims 31-44 on the merits.

In the event that this paper is not timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 01-2340. Applicants believe that no fee is required for this petition. In the event that any fee is required, the fee may be charged to our Deposit Account No. 01-2340.

Respectfully submitted,

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